

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

Device Generic Name: Totally Implanted Spinal Cord Stimulator for Pain Relief.

Device Trade Name: PRECISION™ Spinal Cord Stimulator (SCS) System

Applicant's Name and Address:

Advanced Bionics Corporation
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Premarket Approval Application (PMA) Number: P030017

Date of Notice of Approval to the Applicant: April 27, 2004

II. Indications for Use

The Advanced Bionics PRECISION™ Spinal Cord Stimulator System (PRECISION™ System) is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

III. Contraindications

Patients contraindicated for permanent SCS therapy are those who:

- Have failed trial stimulation by failing to receive effective pain relief
- Are poor surgical risks
- Are pregnant
- Are unable to operate the SCS system

IV. Warnings and Precautions

The warnings and precautions can be found in the "Physician Implant Manual" and the "Physician Lead Manual".

V. Device Description

The Advanced Bionics PRECISION™ Spinal Cord Stimulator System (PRECISION™ System) includes a 16-output, multi-channel implantable pulse generator (IPG) with a rechargeable battery power source. The IPG is connected, either directly or with a lead extension, to either a single 8-contact lead or dual 8-

contact leads. The IPG is controlled by patient and physician programmers. The IPG is implanted in a subcutaneous pocket, and receives radio frequency (RF) programming signals from an external programmer. The IPG decodes the RF signals and delivers stimulation pulses to the patient via a selected combination of output electrodes. The IPG is powered by a hermetically sealed rechargeable battery enclosed within a hermetically sealed titanium case and uses an integrated circuit to generate electrical stimulation. The PRECISION™ System consists of the following specific components:

Implantable Pulse Generator - Model SC-1100

The IPG enclosure is made of titanium alloy, with the dimensions of 55 mm (height), 46 mm (width) and 11 mm (thickness). It is hermetically sealed. The IPG is designed to produce a capacitively coupled monophasic or biphasic rectangular output pulse. The IPG is current regulated and includes programmable coverage areas with each individual electrode contact limited to 12.7 mA. A programming interlock is enforced to limit the coverage area output current to 20 mA or less. The IPG is capable of producing pulse widths between 20 and 1000 µs and frequencies between 2 and 1200 Hz.

The IPG is powered by a radio-frequency (RF) rechargeable lithium ion battery (single cell) for power. The specifications for the implantable battery are as follows:

Capacity: 180 mAh minimum
Nominal voltage: 3.6 V
Enclosure: Hermetic enclosure; no vent

As an internal safety feature the polymer separator inside the battery will permanently disable the battery if the battery temperature exceeds a certain threshold. As an external safety feature a 0.5 Ampere fuse is connected to one battery terminal using a wire with water-tight insulation so that in case of body fluid ingress into the IPG, the fuse will open the battery circuit.

Linear™ Electrode Array Leads - Model SC-2108-xxM

The “xx” in the model number indicates that the lead comes in lengths of 30, 50, and 70 cm. The electrode array leads have an 8-contact in-line design. The distal end of the array consists of 8 evenly spaced Platinum/Iridium (90/10) ring electrodes. The lead is made of polyurethane, the conductor is MP35N silver core wire and the insulation is ETFE. The lead diameter is 0.053 inches and the typical impedance is less than 5 ohms.

Linear™ Lead Extension - Model SC-3108-xx

The “xx” in the model number indicates that the extension comes in lengths of 15, 25 and 35 cm. The lead extension has an in-line 8 contact female connector and set

screw mechanism for retention of connecting the lead. The extension is made of polyurethane with a silicone connector boot and silicone adhesive. The conductor is MP35N silver core wire and the insulation is ETFE. The lead extension diameter is 0.053 inches and the typical impedance is less than 5 ohms.

External Trial Stimulator (ETS) - Model SC-5100

The ETS is intended to provide trial stimulation with the surgically placed electrode array before the implantation of the IPG. It is designed to be worn on the body, provides the identical stimulation capability as the implant, and has the same stimulation control as the Remote Control.

Remote Control (Handheld Programmer) - Model SC-5200

The Remote Control is a hand-held, battery operated assembly that uses infrared (IR) and RF signals to communicate with and program the IPG and ETS. It allows for two-way communication with the IPG for purposes of programming the stimulation output parameters and receiving feedback from the IPG. The Remote Control allows clinicians to set output stimulation parameters that best provide pain relief for patients. It also allows the user to select individual pre-set stimulation parameters within physician prescribed ranges.

Charger - Model SC-5300

The Charger assembly is used to transcutaneously charge the IPG battery. It is a portable device powered by a rechargeable battery and can be held in one hand. The Charger has an internal sound generator to indicate IPG and Charger alignment. A back-telemetry link from the IPG communicates to the Charger when the IPG is fully charged. The Charger can be attached to the patient using double-sided adhesive pads. There are two electrical contacts at the bottom surface of the Charger for its connection to the Base Station, used during recharging of the Charger battery.

Base Station - Model SC-5305

This assembly connects to a universal, wall-mounted transformer and is used to recharge the Charger.

Clinician Programmer with BionicNAVIGATOR™ - Model SC-7150

An off-the-shelf notebook computer is used to facilitate communication with, and programming of, the IPG, the ETS and the Remote Control. The computer is Windows compatible. The software, proprietary to Advanced Bionics, is known as BionicNAVIGATOR™ software. It is used to program the patient output stimulation settings of the IPG. The computer also has a database capability to archive patient programming and pain measurement information. It includes a Graphic Module to identify pain and paresthesia areas using a visual representation of the anatomical

coverage areas. The software can be used by the clinician in the operating room to assess lead position and evaluate paresthesia coverage during surgery.

Accessories

Accessories provided with the PRECISION™ System include the following:

- Torque Wrench - used to tighten the set screws that lock the lead into the IPG
- Suture Sleeve – slides onto the lead and is sutured to the supraspinous ligament or deep fascia
- IPG Template – guides the surgeon to create the correct sizing of the subcutaneous pocket
- Insertion Needle – used during implant surgery to introduce the lead between the vertebra into the epidural space
- Lead Blank – optionally used during surgery to clear a path for the introduction of the lead into the epidural space.
- OR Cable and OR Cable Extension – connected to the ETS for use during the trial phase
- Tunnel Tool – creates a subcutaneous tunnel from the IPG site to the midline incision
- Straight Stylet and Curved Stylet – used to ‘steer’ the lead into place
- Travel Case for Charger/Base Station
- IPG Connector Plug
- Velcro Charging Belt
- Belt Clip Holster
- Charger Adhesives
- Remote Control Battery
- Transformer
- Carrying Case

VI. Alternative Practices

Alternative practices to the use of totally implanted IPGs for spinal cord stimulation to treat chronic pain of trunk and limbs include:

Non-Surgical Treatment Options for Chronic Pain

- Oral medication
- Rehabilitative therapy
- Transcutaneous electrical nerve stimulation (TENS)
- Behavior modification
- Neurolysis (i.e. Therapeutic nerve block, Cryoanalgesia, RF Lesioning)

Surgical Treatment Options for Chronic Pain

- Sympathectomy – severing the nerve pathway
- Partially implanted spinal cord stimulation (SCS) systems – RF implantable spinal cord stimulators (the power source in this system is external)
- Commercially available fully implanted SCS Systems.

VII. Marketing History

The Advanced Bionics PRECISION™ Spinal Cord Stimulation System has not been marketed in the United States or any foreign country.

VIII. Potential Adverse Effects of the Device on Health

Potential risks are involved with any surgery. The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include battery leakage, device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits, and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur.
- Skin erosion or seroma at the IPG site can occur over time.

- Possible surgical procedural risks are: temporary pain at the implant site, infection, spinal cord compression, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma, and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, and lead dislodgement.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, the implant may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation may be experienced.
- Persistent pain at the IPG or lead site.

IX. Summary of Preclinical Testing

A. IPG

Environmental Testing

The following testing was performed to simulate the environmental conditions the device may encounter during normal usage: RF telemetry range, mechanical shock, random vibration, squeeze pressure, operating temperature cycling, high and low temperature storage, high and low pressure storage, electrosurgery exposure, MRI exposure, diagnostic X-ray immunity, ultrasonic imaging immunity, defibrillation immunity, residual gas analysis, and destructive physical analysis.

Device function testing was performed as follows:

- telemetry was verified by separating the devices at 18 inches at an orientation of 0, ± 45 , ± 90 and ± 180 degrees;
- shock testing was conducted at a level of 500 g with a 1.0 msec half-sine pulse duration to each of the six device axes;
- random vibration per EN 45502-1 Section 23.2;
- orthogonal force of 45 N to the IPG case on a flat table surface as per IEC 60601-1;

- temperature cycling of 0°C to 55°C with transition times per MIL STD 833 Method 1010, condition B;
- storage temperatures of -20°C to 55°C;
- storage pressure of 70 and 200 kPa;
- exposure to bipolar electrocautery in a suitable animal model;
- exposure to 1.5 Tesla MRI for 10 minutes;
- exposure to 7000 rad x-rays;
- exposure to ultrasonic energy for one hour in a suitable animal model;
- exposure to a defibrillation source per EN-45502-1 Section 20.2; and
- visual inspection of all components.

Testing demonstrated that the IPG operated according to specification after exposure to the specific conditions identified.

Hermeticity

A residual gas analysis was performed and demonstrated that the maximum moisture content via mass spectral analysis does not exceed 4,000 ppm. Hermeticity was verified after a battery short between the terminals of a fully charged battery, by demonstrating that the IPG case showed no signs of damage, was within mechanical thickness tolerance and met the hermeticity specification ($\leq 3 \times 10^{-9}$ cc-atm/sec He).

Electrical Characterization

Characterization of the electrical design of the IPG was performed. The testing included variations in temperature, supply voltage, load resistance, output current, pulse width and frequency. Characterization of the output along the impedance/current curve under loads from 300 to 1200 ohms was performed. Results verified that the IPG system performed in accordance with design specifications.

Header Adhesion Testing

The IPG Header underwent testing on temperature cycling, vertical peel, rotational testing, wall thickness integrity, adequate adhesion of cast epoxy header to the titanium case, suture hold strength, contact resistance, insertion/withdrawal force, insertion/withdrawal durability, connector locking force, connector resistance in motion, connector vibration, corrosion soak, and thermal shock to the antenna coil. The IPG header met all required acceptance criteria.

IPG Hybrid

The IPG Hybrid met performance specifications for the following tests: crystal frequency, internal RAM, A/D and voltage regulation, quiescent current, transmitting and receiving current, reset, output current calibration,

switching regulation, battery charging circuit, software default setup, monopolar amplitude and timing, bipolar passive and active amplitude, slow start, burst on and rest, bipolar and monopolar impedance, RF telemetry, stimulating current and battery protection circuitry. Accelerated life test of this assembly was performed at 125°C for 1000 hours.

B. Battery Testing

The implantable battery successfully met performance criteria for the following bench tests: temperature storage, random vibration, mechanical shock, humidity, drop, atmosphere pressure, terminal lead pull strength, accelerated service life, self discharge/storage loss, deep discharge, short circuit test in air and abnormal charging test in air. The implantable battery was further tested inside an improvised isolating chamber (beef steak surrounding the IPG, inside a glass bottle surrounded by water) for normal charging, abnormal charging, and discharging. The testing met performance acceptance criteria.

Implantation in a Pig

The IPG with the implantable battery was implanted in a 145 lb male pig. The battery inside the IPG was charged for 75 minutes, until the temperature of the IPG stabilized. The battery voltage increased from 3.30 V to 3.60 V and the IPG case temperature rose 2.8°C while the IPG can (bottom) temperature rose 1.1°C. This result met performance acceptance criteria.

Clinical Experience

Clinical experience with the device in 26 subjects demonstrated that the audio and visual cues from the PRECISION™ System charger were adequate for the volunteers to follow in order to recharge the implantable battery inside the IPG. The maximum recharge time was four hours.

Longevity

Results of 9 months of modeling the different modes of battery use-- low, medium, high and accelerated-- indicate that the implantable battery has sufficient capacity for the claimed clinical use. The estimated longevity is 5 years when used at medium use.

C. Electrode Lead Array and Extension

The electrode lead array was tested on sterilization durability, insertion/withdrawal of insertion needle, insertion/withdrawal of stylet, suture sleeve compatibility, connector configuration, connector leakage, destructive pull test pre-soak and post-soak, conductor wire flex test wet, connector wire flex test dry, fluoroscopic visibility, and animal model evaluation. The lead extension was tested for sterilization durability, temperature cycling, insertion/withdrawal durability of connector stack assembly,

insertion/withdrawal and durability of proximal lead end, locking force, contact resistance, set screw torque and locking force, vibration, tunnel survivability, destructive pull, and corrosion soak. The lead and extension both met all performance acceptance criteria.

D. Programmer Testing

Remote Control testing included functionality verification, operating temperature, storage temperature, temperature cycle, humidity, shipping, random vibration, drop, enclosure mechanical strength, mechanical shock, and impact. Software was developed and meets the recommendations provided in the Food and Drug Administration (FDA) guidance, entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

E. External Trial Stimulator

The External Trial Stimulator underwent the following tests: specified functionality, RF telemetry, operating temperature, storage temperature, temperature cycle, humidity, shipping, random vibration, drop, enclosure mechanical strength, mechanical shock, impact, connector insertion/extraction, device cleaning, battery spring fatigue, and battery door fatigue. The device met performance acceptance criteria for each test.

F. Electromagnetic Compatibility (EMC) Testing

The PRECISION™ System has been evaluated for effects on its functioning and/or programming by external sources of interference in accordance with all applicable sections of IEC 60601-1-2 "Medical Electrical Equipment - Part 1: General Requirements for Safety: Electromagnetic Compatibility-Requirements and Tests." Testing included radiated emissions, RF immunity, magnetic immunity, and electrostatic discharge. The test results met the requirements of the applicable sections of the standard.

G. Charger and Base Station

Testing included functional verification, Base Station spring coil contact fatigue, Base Station connector fatigue, impact, enclosure mechanical strength, random vibration, drop, operating temperature, storage temperature, temperature cycle, humidity, moisture resistance, device cleaning, and shipping. The test results met the performance criteria requirements.

H. Surgical Accessories

Functionality and durability of the Tunnel Tool, OR Cable, Insertion Needle, Lead Blank, and the Suture Sleeve were demonstrated by tests designed to simulate clinical use.

I. Hazard Analysis

Hazard analysis was performed and identified risks were adequately mitigated or eliminated. Hazard analysis was performed in accordance to EN1441 and ISO14971. Identified risks were adequately eliminated or mitigated.

J. Reliability Testing

Tests have been completed to assess the long-term reliability of system components including the IPG, electrode array, lead extension and suture sleeve. The results were consistent with the specified reliability targets. Results demonstrated annual reliability $\geq 99\%$ for greater than or equal to 5 years.

K. Sterilization and Shelf Life

The implantable components of the PRECISION™ System are designed to be single-use only. The implantable components of the PRECISION™ System are sold sterile with a sterility assurance level (SAL) of 10^{-6} .

L. Biocompatibility

All patient-contact materials met the biocompatibility requirements of "ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. Second Edition."

M. Package Qualification

System components passed the associated test requirements after being subjected to International Safe Transit Association (ISTA) Test Procedure 1A.

N. Animal Testing

The objectives of a 30-day and 90-day animal model were to validate the surgical implantation, telemetry features, impedance stability, charging features, stimulation programming, and biocompatibility of the PRECISION™ System. The objectives were all met.

X. Summary of Clinical Studies

The clinical data summarized below was based on available peer reviewed published literature for similar implantable spinal cord stimulation (SCS) systems. The PRECISION™ System is similar to the SCS systems reported in the published literature in intended use, target patient population, technology, device design and output characteristics. Three key studies, which met effectiveness specific inclusion and exclusion criteria, were included in the effectiveness analysis. A total of 11 studies, which met safety specific inclusion and exclusion criteria, were included in the safety analysis. The effectiveness data represents a total of 116 patients that were implanted with SCS systems, while the safety data represents a total of 1056 intent-to-treat patients and 880 permanently implanted patients.

A. Objectives of the Studies

Based on nonclinical studies that demonstrated the PRECISION™ System has comparable output characteristics to the commercially available SCS systems reported in the literature, the primary objective was to provide clinical evidence of the effectiveness of the PRECISION™ System, using literature articles, for the relief of failed back surgery syndrome, intractable low back, and limb pain.

Effectiveness endpoints were demonstrated by a 50% reduction in pain using the visual analog scale (VAS). Safety of the PRECISION™ System was established using literature articles, for the relief of failed back surgery syndrome, intractable low back, and limb pain. This was accomplished by examining the incidence of complications of the SCS systems used in the published literature, Medical Device Reports and actual experience with the PRECISION™ System in a clinical trial.

B. Effectiveness

Three (3) clinical literature studies were used to assess the effectiveness of the PRECISION™ System (Ohnmeiss et al. 1996, Villavicencio et al. 2000 and Hassenbusch SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was considered in the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, an identified totally implanted SCS was used in association with a percutaneous and/or surgical lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the PRECISION™ System.

- The prospective study by Ohnmeiss et al. 1996 examined the long-term effectiveness of SCS in patients with intractable leg pain. A total of 40 patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, sickness impact profile (SIP), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was also performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had a greater than 50% improvement in their pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Also, 3 patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

- The prospective study by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In the study, 27/41 (66%) patients had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%) patients reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, 1 patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

- A retrospective analysis by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg

with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and/or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. A total of 5 (19%) patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were 4 (10%) patients that underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" In this study, 16/26 patients (62%) had greater than 50% pain relief with SCS. A total of 2/16 (13%) patients had greater than 50% pain relief with opioids. Mean follow-up was 2.1 ± 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In the Hassenbusch study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

The output of the PRECISION™ System is within the range of the output parameters of the SCS devices and associated leads reported in the retrospective literature evaluation. The PRECISION™ System may produce a lower output stimulation amplitude when compared to literature but this can be compensated for by the increased pulse width range available with the PRECISION™ System. Instructions for use will ensure that energy output is adequate to achieve optimum effectiveness.

C. Safety

Eleven studies with detailed inclusion/exclusion criteria were used to demonstrate the safety of the PRECISION™ System evaluation. The studies included a total of 1056 intent-to-treat patients and 880 patients receiving implants. It should be noted that citations cover both IPG and RF systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems. The table below contains the percentage of patients reporting the indicated types of adverse events.

Table 1 - Summary of Risks Identified in Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%
Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Table 2 - Numbers (%) of Patients with Surgical Interventions as Identified in Retrospective Clinical Studies

Risks	No. Adverse Event	No. Patients N = 1648
Lead Replacement/Explant	77	77 (4.7%)
Lead Repositioning	96	67 (4.1%)
IPG Replacement/Explant	14	14 (0.1%)
IPG Repositioning	8	8 (0.1%)
Component Replacement/Explant*	61	61(3.7%)
Component Repositioning*	8	8 (0.1%)

*Specific Component not specified

D. MDR and MAUDE Database

The search covered from January 1, 1989 to June 27, 2003. Search criteria included Itrel, Synergy, Genesis, Pisces, Octad, Quattrode, Octrode and Cervitrode. All non-spinal cord stimulating indications and reports associated with non-fully implantable systems were excluded. Non-device related reports were also excluded, such as alleged surgeon incompetence or using expired sterile product. The search gave 1388 reports.

Table 3 - Number of MDR and MAUDE reported events

Event category	# Events	% Total events
Lead migration	23	1.57
Infection/perioperative infection	79	5.40
Epidural hematoma/hemorrhage	4	0.27
Seroma	2	0.14
Hematoma	0	0.00
Paralysis	5	0.34
CSF leak	1	0.07
Intermittent stimulation	129	8.82
Over/under stimulation; ineffective therapy	144	9.84
Shock	120	8.20
Pain	36	2.46
Allergic/tissue reaction	6	0.41
Skin erosion	3	0.21
Lead breakage/lead failure	540	36.91
Hardware malfunction	188	12.85
Loose connection	1	0.07
Other	86	5.88
Battery failure	65	4.44
Expected battery EOL	11	0.75
Unknown	20	1.37
Total	1463	100.00

E. Actual Clinical Experience

Clinical data has been collected during a clinical study of the PRECISION™ System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the PRECISION™ System. The follow-up period for the 26 implanted patients ranged from 2 weeks to 6 months. The following major adverse events were reported.

Table 4 – Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced
Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

XI. Conclusion Drawn from the Studies

The review and analyses documented in the clinical report demonstrated the safety and efficacy of the PRECISION™ System. The results from the literature of similar devices, combined with the nonclinical testing on the PRECISION™ System are expected to outweigh any risks and provides reasonable assurance that the PRECISION™ System is safe and effective when used to aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

XII. CDRH Decision

The determination of the safety and effectiveness of the PRECISION™ System was based on available published clinical studies for similar implanted spinal cord stimulation systems. FDA has concluded that these available published clinical studies constitute valid scientific evidence for the purposes of determining safety and effectiveness. Upon completion of the evaluation of the information submitted in this PMA, FDA has concluded that the PRECISION™ System is sufficiently similar to the SCS systems reported in literature in regard to intended use, targeted patient population, technology, device design, and electrical output characteristics. FDA has determined that this evidence, when combined with the nonclinical data included in the PMA, provide reasonable assurance of the safety and effectiveness of the PRECISION™ System for treating chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. Furthermore, FDA inspections of the manufacturing facilities demonstrated that all sites involved in the manufacture of the PRECISION™ System are in compliance with the Quality System Regulation.

In arriving at this conclusion, FDA has taken into consideration, as required under section 205 of the Food and Drug Administration Modernization Act of 1997, the

least burdensome means to market, while maintaining the statutory threshold for approval of a PMA, i.e., reasonable assurance of safety and effectiveness.

FDA issued an approval order on April 27, 2004.

The sponsor's manufacturing facilities were inspected and determined to be in compliance with the Quality System Regulation (21 CFR Part 820).

XII. Approval Specifications (To be completed by FDA)

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.

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